

the payment for burn patients on mechanical ventilation in the future.

c. Multiple Level Spinal Fusion

Prior to the publication of the proposed rule, we received a comment recommending the establishment of new DRGs that would differentiate between the number of vertebrae involved in a spinal fusion procedure. The commenter noted that the ICD-9-CM Coordination and Maintenance Committee discussed adding a new series of codes to identify multiple levels of spinal fusions at its December 6, 2002 meeting.

The following codes were approved by the Committee, effective for October 1, 2003, and are listed in Table 6B in the Addendum to this final rule:

- 81.62, Fusion or refusion of 2-3 vertebrae
- 81.63, Fusion or refusion of 4-8 vertebrae
- 81.64, Fusion or refusion of 9 or more vertebrae

The commenter conducted an analysis to support redefining the spinal fusion DRGs using these new ICD-9-CM codes. Using the CMS FY 2001 Standard Analytical File data for physicians and hospitals as the basis for its analysis, the commenter linked a 5-percent sample of hospital spinal fusion cases with the corresponding physician claims. Because there were no ICD-9-CM codes to identify multiple level fusions in 2001, multiple level fusions were identified using Current Procedural Terminology (CPT) codes on the physician claims.

The analysis found that increasing the levels fused from 1 to 2 levels to 3 or more levels increased the mean standardized charges by 38 percent for lumbar/thoracic fusions, and by 47 percent for cervical fusions. The commenter then recommended redefining the spinal fusion DRGs to differentiate between 1 to 2 level spinal fusions and multilevel spinal fusions.

The following current spinal fusion DRGs separate cases based on whether or not a CC is present: DRG 497 (Spinal Fusion Except Cervical With CC) and DRG 498 (Spinal Fusion Except Cervical Without CC); and DRG 519 (Cervical Spinal Fusion With CC) and DRG 520 (Cervical Spinal Fusion Without CC). The difference in charges associated with the current CC split is only slightly greater than the difference attributable to the number of levels fused as found by the commenter's analysis. Therefore, in the May 19, 2003 proposed rule, we did not propose to redefine these DRGs to differentiate on the basis of the number of levels fused.

We note that adopting the commenter's recommendation would necessitate adjusting the DRG relative weights using non-MedPAR data, because Medicare claims data with the new ICD-9-CM codes will not be available until the FY 2003 MedPAR file. Although we considered this possibility, we believe the more prudent course, given that the current DRG structure actually appears to differentiate appropriately among these cases, is to wait until sufficient data with the new multilevel spinal fusion codes are available before making a final determination on whether multilevel spinal fusions should be incorporated into the DRG structure.

Comment: Several commenters supported our proposal to wait for data using the new ICD-9-CM procedure codes for multiple level spinal fusions prior to making revisions to the spinal fusion DRGs. One commenter representing hospitals supported our proposal to continue with the current DRG classification system until sufficient data are available to evaluate a potential DRG change. Several commenters expressed their appreciation for the creation of the new codes for multiple level spinal fusion. They recognized the difficult challenge that was involved in developing this new classification system as part of ICD-9-CM.

One commenter requested us to proceed with a DRG revision for multiple level spinal fusion without waiting for data using the new codes. This commenter stated that there are significant costs involved with increased instrumentation and hardware when multiple level spinal fusions are performed, and requested that we consider using non-MedPAR data to establish relative weights for new DRGs based on the levels of vertebrae involved. In addition, the commenter stated that there is a need to distinguish between fusions and refusions within the DRGs. The commenter stated that refusions vary significantly due to the existence of scar tissue and implants that need to be removed and replaced. Further, the commenter recommended that we split DRG 496 Combined anterior/posterior spinal fusion based on the presence or absence of a complication or comorbidity.

Response: We appreciate the support of commenters that we wait for data from the reporting of the new codes for multiple level spinal fusion prior to proposing revisions to the spinal DRGs (rather than using non-MedPAR data prior to the availability of data using the new codes). We also appreciate the comments concerning the extensive

effort it took on our part to develop a set of ICD-9-CM codes that could capture this type of information. We believe it is important to carefully examine hospital data prior to making any revisions for multiple level spinal fusions. Therefore, we will look at this data as we receive it and evaluate any need for DRG revisions. We will consider all the points raised by the commenters as we consider additional DRG revisions for spinal fusions in the future.

d. Heart Assist System Implant

During the comment period for the FY 2003 IPPS proposed rule on which the FY 2003 IPPS final rule was based, we received a suggestion from a commenter that we develop a new heart transplant DRG entitled "Heart Transplant with Left Ventricular Assist Device (LVAD)." The commenter stated that, because a great number of LVAD cases remain inpatients until heart transplant occurs, there is a disparity in costs between heart transplant patients who receive LVADs during the stay and those who do not. Cases in which heart transplantation occurs during the hospitalization are assigned to DRG 103 (Heart Transplant). Therefore, the costs of these LVAD cases where a heart transplant is also performed during the same hospitalization are included in the DRG relative weight for DRG 103. Accordingly, we did not create a new DRG for these cases. However, we noted that we would continue to monitor these types of cases.

When we reviewed the FY 2002 MedPAR data, we identified only 21 cases in DRG 103 that listed a procedure code indicating the use of any heart assist system. We do not believe that 21 cases is a sufficient number of cases to support creation of an additional DRG. Therefore, in the May 19, 2003 proposed rule, we did not propose a change to the structure of either DRG 103 or DRG 525.

Comment: Two commenters argued that procedure code 37.66 (Implant of an implantable, pulsatile heart assist system) does not fit clinically or financially with the following other procedure codes in DRG 525:

- 37.62, Implant of other heart assist system,
- 37.63, Replacement and repair of heart assist system,
- 37.65, Implant of an external, pulsatile heart assist system
- 37.66, Implant of an implantable, pulsatile heart assist system.

One commenter indicated that, according to an analysis that it performed, Medicare data on procedure code 37.66 demonstrates that average charges (\$342,725) and length of stay